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VIA E-MAIL AND HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
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Re: Constitutional Validity of the Food and Drug Administration's Regulations, Guidances, Policies, and Practices, in Light of Recent First Amendment Case Law, Docket No. 02N-0209 (67 Fed. Reg. 34942, May 16, 2002)

To Whom It May Concern:

Enclosed please find comments, submitted on behalf of the Freedom to Advertise Coalition, in response to the Food and Drug Administration's call for comments regarding the constitutional validity of its policies in light of recent First Amendment case law.

Sincerely,

Daniel A. Kracov

Counsel to the Freedom to Advertise Coalition

Enclosure

02N-0209

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BEFORE THE FOOD AND DRUG ADMINISTRATION

Constitutional Validity of the Food and Drug Administration's Regulations, Guidances, Policies, and Practices, in in Light of Recent First Amendment Case Law (Response to 67 Fed. Reg. 44942 (May 16, 2002))	**Docket No. 02N-0209**

Comments of the Freedom to Advertise Coalition

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Table of Contents

Constitutional Validity of the Food and Drug Administration's Regulations, Guidances, Policies, and Practices, in Light of Recent First Amendment Case Law
Docket No. 02N-0209 (67 Fed. Reg. 34942 May 16, 2002)

These comments are filed by the Freedom to Advertise Coalition ("FAC") in response to the Food and Drug Administration's ("FDA's") request for comments on whether the FDA's regulatory policies are constitutional in light of recent First Amendment case law.[1] FAC was established in 1987 out of concern for the right to truthfully and non-deceptively advertise all legal products. The concerns of FAC are not limited to specific product categories but are more fundamental in nature. FAC works to protect the rights of commercial free speech guaranteed by the Constitution for all legal products and services. FAC members include the American Advertising Federation, the American Association of Advertising Agencies, the Association of National Advertisers, the Magazine Publishers of America, the Outdoor Advertising Association of America, and the Point of Purchase Advertising Institute.

FAC applauds the FDA for requesting public comments on this fundamental issue. Free speech forms the bedrock of American values, and FDA's initiative in calling for comments is refreshing. The free flow of commercial speech, like other forms of speech, is appropriately protected by the First Amendment simply because "it is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed."[2] However, the protection of commercial speech is particularly important where, as here, suppression of speech could negatively impact consumers' health. For example, when FDA imposes overly restrictive policies on advertising or labeling claims about a product's potential to reduce the risk of disease, prevent disease, or mitigate the effects of disease, FDA does more than just violate the First Amendment – it prevents consumers from receiving key health information. We believe that FDA's mission of protecting the public health is critical, and it can be accomplished and advanced with careful consideration of First Amendment values.

Accordingly, FAC urges FDA to issue formal procedures requiring FDA to perform a written First Amendment analysis for every decision that potentially restricts, suppresses, or infringes on commercial speech.

I. Executive Summary

The comments that follow provide an overview of First Amendment case law on commercial speech and a summary of recent pivotal cases directly involving FDA. The comments then address the questions in FDA's request for comments that are of particular concern to FAC's members. Although most of the discussion herein pertains to advertising, the comments touch upon related

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[1] *See* FDA's Notice; Request for Comments, 67 Fed. Reg. 34942 (May 16, 2002); 67 Fed. Reg. 45742 (July 10, 2002) (extending the deadline for comments).

[2] *Thompson v. Western States Med. Ctr.*, 122 S. Ct. 1497, 1503 (2002) (citing *Virginia State Bd. of Pharmacy v. Virginia Citizen's Consumer Council*, 425 U.S. 748, 765 (1976)).

labeling issues because FDA, at times, has interpreted "labeling" broadly to include activities of our constituents, such as point-of-purchase advertising and Internet promotions.[3]

As an initial matter, FAC agrees with those that recently have argued that infringement on truthful, nonmisleading commercial speech, like infringement on noncommercial speech, should be reviewed under strict scrutiny, rather than intermediate scrutiny. FAC believes that commercial speech is just as important in the marketplace of ideas as noncommercial speech and is aware that evidence indicates that the initial framers of the Constitution did not distinguish between the two.[4] Indeed, in a concurring opinion in *44 Liquormart, Inc. v. Rhode Island*,[5] Justice Thomas declared: "I do not see a philosophical or historical basis for asserting that 'commercial' speech is of 'lower value' than 'noncommercial' speech."[6] In addition, other Justices have expressed discomfort with the intermediate level of scrutiny reserved for commercial speech, acknowledging the Court's "longstanding hostility" towards the regulation of truthful, nonmisleading commercial speech.[7] Nevertheless, stringent application of the intermediate scrutiny standard, first articulated in *Central Hudson Gas & Electric Corp. v. Public Service Commission*,[8] has been sufficient to strike down the suppression of truthful, nonmisleading commercial speech in recent cases, and therefore, the Supreme Court has not needed to break new ground.[9] (*See* Section II(A) herein). Thus, in general, FDA must evaluate its regulatory actions that implicate commercial speech with stringent application of the four-part test in *Central Hudson*.[10]

Under *Central Hudson*, the critical third and fourth prongs, respectively, require the government to bear the burden of proving that its regulatory policy *directly* and *materially* advances the government's interests and that its policy is "no more extensive than necessary" to achieve its interests.[11] Just this

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[3] *See, e.g.*, FDA Warning Letter to Ocean Spray Cranberries, Inc. ("Ocean Spray"), dated Jan. 19, 2001; *see infra*, discussion at Section VIII.

[4] *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 522 (1996) (Thomas, J., concurring).

[5] 517 U.S. 484 (1996).

[6] *Id.* at 521 (Thomas, J., concurring).

[7] *Id.* at 509-514 (joint opinion of Stevens, J., Kennedy, J., and Ginsburg, J.); *see id.* at 517 (Scalia, J., concurring) (sharing Justice Thomas' discomfort with *Central Hudson*); *see also Western States*, 122 S. Ct. 1509 (Thomas, J., concurring) (suggesting that strict scrutiny should be applied in commercial speech cases where the governmental interest is achieved by keeping the public in the dark); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001) (noting that the petitioners urged the Court to apply strict scrutiny to a commercial speech cases); *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 197 (1999) (Thomas, J., concurring) (suggesting that strict scrutiny should be applied in commercial speech cases where the governmental interest is achieved by keeping the public in the dark).

[8] 447 U.S. 557, 566 (1980).

[9] *See, e.g., Lorillard Tobacco*, 533 U.S. at 555.

[10] *Central Hudson*, 447 U.S. at 566.

[11] *See Western States*, 122 S. Ct. at 1504 (reconfirming the application of *Central Hudson*); *Lorillard Tobacco*, 533 U.S. at 555 (following *Edenfield v. Fane*, 507 U.S. 761, 777 (1993) and finding that "a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree); *see also Greater New Orleans*, 527 U.S. at 182 ("[T]he party seeking to uphold a

term, *Thompson v. Western States Medical Center*,[12] clarified under the fourth prong of the test that if the government can "achieve its interests in a manner that does not restrict speech, or restricts less speech, the [g]overnment must do so."[13] This ruling has broad ramifications because, in the past, the Court would uphold a regulatory policy merely if the government could demonstrate a "reasonable fit" between its means and ends.[14] Moreover, *Edenfield v. Fane*[15] has long stood for the proposition that, under the third prong, the government must have concrete evidence that demonstrates that a restraint on commercial speech *directly*[16] advances its interests to a *material* degree.[17]

Accordingly, to ensure that its regulatory policies that implicate commercial speech do not run afoul of the First Amendment, under *Central Hudson*, FDA must have concrete evidence that its policies directly and materially advance its interests, and it must be able to demonstrate that its chosen policies restrict no more speech than necessary.

In addition, FDA must apply the even more stringent test, in *Southeastern Promotions Ltd. v. Conrad*,[18] to the least tolerable restrictions on speech -- prior restraints (*e.g.*, pre-approval systems). FDA also must apply the test in *United States v. United Foods, Inc.*[19] to compelled disclosures and reject those that are *unnecessary* to avoid consumer confusion, as unconstitutional.

In accordance with these First Amendment parameters, FAC's primary concerns are as follows:

- FAC believes that FDA should issue formal procedures requiring FDA to perform a written First Amendment analysis for every decision that potentially restricts, suppresses, or infringes on commercial speech.

    - To ensure that its general commercial speech restrictions do not run afoul of the First Amendment, under *Central Hudson*, FDA must have concrete evidence that its policies directly and materially advance its interests, and it must be able to demonstrate that its chosen policies restrict no more speech than necessary.

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restriction on commercial speech carries the burden" of demonstrating that the last three steps under *Central Hudson* are met).

[12] 122 S. Ct. 1497 (2002).

[13] *Western States*, 122 S. Ct. at 1506.

[14] *See, e.g.*, *Lorillard Tobacco*, 533 U.S. at 561.

[15] 507 U.S. 761 (1993).

[16] *See id.* at 777 (the government must have concrete evidence that a restraint directly advances its interests).

[17] *See id.* at 770-71 (restrictions on commercial speech must alleviate the asserted harm to a material degree); *Lorillard Tobacco*, 533 U.S. at 555 (citing *Edenfield* for this proposition).

[18] 420 U.S. 546, 558-59 (1975).

[19] 533 U.S. 405, 416 (2001).

For example, FDA should scrutinize its reluctance to apply the holding in *Pearson v. Shalala*,[20] which concerned dietary supplements, to conventional foods. There, the D.C. Circuit reconfirmed that disclaimers are preferable to suppression of speech and held that the First Amendment does not permit FDA to rely upon the "significant scientific agreement" standard to restrict health claims for dietary supplements, unless it can demonstrate that a disclaimer would not adequately advance its interest. FDA's reluctance to apply this holding in the context of conventional foods will render the application of the "significant scientific agreement" standard in many instances -- more extensive than necessary -- in violation of the First Amendment. (*See* Section VI herein).

- To ensure that its compelled speech requirements do not run afoul of the First Amendment, under *United Foods*, FDA must ensure that any required disclaimers, qualifying information, and warnings are absolutely necessary to prevent consumers from being misled.

  This principle is particularly important in the context of prescription drug advertising. The Federal, Food, Drug, and Cosmetic Act, and its implementing regulations, compel the disclosure of detailed safety information in print and broadcast prescription drug ads. To the extent that these safety disclosures are *necessary* to prevent the ads from being misleading, they are consistent with the First Amendment, under *United Foods*. However, in some instances, the advertising disclosure requirements contain more safety information than necessary. For example, the *brief summary* information required for print ads contain some information that consumers do not need. This *unnecessary* information can obscure the essential safety information. Eliminating unnecessary disclosure requirements would prevent consumers from ignoring lengthy disclosure information altogether. (*See* Section IV herein).

- To ensure that its "voluntary" and mandatory pre-approval requirements for prescription drug ads and initial launch ads are not characterized as *de facto* or *de jure* prior restraints, under *Southeastern Promotions*, FDA should ensure that these policies are truly voluntary. Moreover, to prevent these pre-approval processes from giving FDA unbridled discretion to reject proposed ads, in violation of the advertisers' First Amendment rights, FDA should incorporate procedural safeguards. FDA should have a formal process for voluntary submissions that, at minimum, delineates FDA's decision criteria and prescribes an FDA decision timetable. In addition, when rejecting an ad, FDA should be required to provide *empirical evidence* forming the basis for its rejection. FDA should not have unbridled discretion to reject ads that are truthful and nonmisleading and those that meet FDA's *constitutional* compelled speech requirements. (*See* Section VII herein).

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[20] 164 F.3d 650 (D.C. Cir. 1999).

- FAC applauds FDA's issuance of guidance documents in the late 1990s clearly permitting direct-to-consumer ("DTC") drug advertising. Empirical data show that FDA's regulatory policy permitting DTC advertising is advancing FDA's interest in protecting the public health. Specifically, DTC advertising: (1) improves the public health, (2) enhances the patient/physician relationship without interfering with the practice of medicine, (3) does not lead to misprescribing or over-prescribing, and (4) adequately communicates risk. Nevertheless, certain DTC advertising policies may be too restrictive. FDA should scrutinize its existing policies to ensure that they are not unnecessarily restrictive in violation of the First Amendment. (*See* Section VII herein).

II. Overview of First Amendment Case Law in the Commercial Speech Context

More than a quarter century ago, the United States Supreme Court held that the freedom of speech guaranteed by the First Amendment to the United States Constitution[21] extends to commercial speech.[22] Of course, this guarantee does not entirely immunize commercial speech from government regulation. Three stages of analysis permit identification of constitutionally impermissible abridgement of protected commercial speech. First, the expression at issue must be identified as commercial speech. Next, the government action must be determined to infringe on commercial speech. Finally, the infringement must be deemed constitutionally impermissible.

A. Identification of Protected Commercial Speech

The Supreme Court, in *Western States,* reaffirmed that commercial speech should be strongly protected by the First Amendment because:

> The commercial marketplace, like other spheres of our social and cultural life provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment.[23]

In recent cases, some have argued that infringement on truthful, nonmisleading commercial speech should be treated the same as infringement on noncommercial speech, and reviewed under the strict scrutiny standard. Commercial speech is just as important in the marketplace of ideas as noncommercial speech. Moreover, Justice Thomas has recognized that evidence indicates that "commercial activity and advertising were integral to life in colonial America and that [the Framers of the Constitution] . . . did not distinguish between commercial and noncommercial messages."[24] Indeed, in his concurring opinion in *44 Liquormart,* Justice Thomas declared: "I do not see a philosophical or historical basis for asserting that 'commercial' speech is of 'lower value' than

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[21] U.S. Const. amend. I.

[22] *See Virginia State Bd. of Pharmacy,* 425 U.S. at 748.

[23] *Western States,* 122 S. Ct. at 1503 (citation omitted).

[24] *44 Liquormart,* 517 U.S. at 522 (Thomas, J., concurring).

'noncommercial' speech."[25] Other Justices also have expressed discomfort with the intermediate level of scrutiny in *Central Hudson*, acknowledging the Court's "longstanding hostility" towards the regulation of truthful, nonmisleading commercial speech.[26]

Nevertheless, because stringent application of *Central Hudson* has been sufficient to strike down the suppression of truthful, nonmisleading commercial speech, the Court has not needed to break new ground.[27] Thus, infringement on commercial speech is still reviewed with intermediate scrutiny under *Central Hudson*, whereas infringement on noncommercial speech (*e.g.*, scientific exchange, political speech, and communications to the press) is reviewed under strict scrutiny. Accordingly, accurate identification of commercial speech is important, not only to guard against government infringement, but also to distinguish it from core protected speech.

The Supreme Court, however, has recognized the "difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category."[28] Such a task is especially challenging since communications frequently present "complex mixtures of commercial and non-commercial elements."[29] Although the Court has not been entirely consistent in its characterizations of commercial speech, its most enduring definition appeared in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*[30] In *Virginia Board*, the Court defined "commercial speech" as "speech which does 'no more than propose a commercial transaction.'"[31] Importantly, in its June, 2001 opinion in *United Foods*,[32] the Court reiterated this, and only this, test. FDA should exercise great care, therefore, when considering any action that may limit either core protected speech or the somewhat less protected category of communications that propose a commercial transaction.

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[25] *Id.* at 521 (Thomas, J., concurring).

[26] *Id.* at 509-514 (joint opinion of Stevens, J., Kennedy, J., and Ginsburg, J.); *see id.* at 517 (Scalia, J., concurring) (expressly sharing Justice Thomas' discomfort with *Central Hudson*); *see also Western States*, 122 S. Ct. 1509 (Thomas, J., concurring) (suggesting that a more rigorous standard should be applied in commercial speech cases where the governmental interest is achieved by keeping the public in the dark); *Lorillard Tobacco*, 533 U.S. at 555 (noting that the petitioners urged the Court to apply strict scrutiny to a commercial speech cases); *Greater New Orleans*, 527 U.S. at 197 (Thomas, J., concurring) (suggesting that a more rigorous standard should be applied in commercial speech cases where the governmental interest is achieved by keeping the public in the dark).

[27] *See, e.g., Lorillard Tobacco*, 533 U.S. at 555.

[28] *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 419 (1993).

[29] *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 81 (1983) (Stevens, J., concurring); *see also Washington Legal Found. v. Friedman*, 13 F. Supp. 51, 62 (D.D.C. 1998), *vacated in part on other grounds*, *Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000) (finding that reprints of scientific articles and textbook excerpts were commercial speech when distributed by pharmaceutical companies, but that they were core protected speech when initially published).

[30] *Virginia State Bd. of Pharmacy*, 425 U.S. 748 (differentiating between "commercial speech" and reporting of news and political commentary); *see Discovery Network*, 507 U.S. at 423 ("the proposal of a commercial transaction" is "*the test* for identifying commercial speech") (quoting *Board of Trustees v. Fox*, 492 U.S. 469 (1989)).

[31] *Id.* at 762 (*quoting Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 385 (1973)).

[32] *United Foods*, 533 U.S. at 409.

Courts that have evaluated the constitutionality of FDA labeling, advertising, and promotion restrictions, such as restrictions on "health claims" for foods and dietary supplements and restrictions on soliciting prescriptions for compounded drugs, have consistently classified the speech at issue as commercial speech.[33] Nevertheless, given the importance of the flow of information for the public health, FDA should carefully consider whether its regulatory policies at times may infringe upon core speech.

B. Identification of Infringement on Commercial Speech

The scope of First Amendment protections of commercial speech is quite broad. It protects organizations, as well as individuals,[34] and preserves the right of prospective audience members to receive the protected speech.[35] The right extends not only to freedom from government restraint of speech, but also to protection from compelled speech.[36]

1. The First Amendment Protects Against Indirect Infringement of Commercial Speech

The First Amendment also prohibits government actions that only indirectly infringe upon commercial speech. Thus, the government may not condition access to benefits or entitlements based upon a prospective recipient's commercial speech or willingness to forgo its expression.[37] As the Supreme Court announced in *Perry v. Sindermann*:[38]

> [E]ven though a person has no 'right' to a valuable government benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis that infringes his constitutionally protected interests – especially his interests in freedom of speech. For if the government could deny a

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[33] *See, e.g., Western States*, 122 S. Ct. at 1504 (reviewing a law prohibiting soliciting for, and advertising, compounded drugs); *Pearson v. Shalala*, 164 F.3d 650, 655-56 (D.C. Cir. 1999) (applying the *Central Hudson* four-prong test to require FDA to consider whether the use of a disclaimer would remedy the potentially misleading nature of "health claims" for dietary supplements); *Washington Legal Found.*, 13 F. Supp.2d at 65 (finding that FDA's restrictions on how pharmaceutical companies could use textbook and journal reprints and educational seminars to promote off-label drug use was unconstitutional).

[34] *See First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 784-86 (1978) (noting that corporate speech is protected by the First Amendment).

[35] *See Virginia State Bd. of Pharmacy*, 425 U.S. at 756-57 (recognizing extension of First Amendment commercial speech protection to both distribution and receipt of information); *Washington Legal Found.*, 13 F. Supp. 2d at 51 (upholding prospective information recipients' First Amendment rights) *vacated on other grounds*, *Washington Legal Found.*, 202 F.3d at 331.

[36] *See supra* discussion at Section II(B)(2).

[37] *See Western States*, 122 S. Ct. 1497 (holding FDA's denial of an otherwise available exemption from penalties that may be levied pursuant to violations of the new drug approval process, due to the advertisement of compounded drug products by a pharmacist, constituted an unconstitutional indirect burden on the pharmacist's commercial speech).

[38] 408 U.S. 593, 597 (1972).

> benefit to a person because of his constitutionally protected speech or associations, his exercise of those freedoms would in effect be penalized and inhibited. This would allow the government to 'produce a result which [it] could not command directly.'[39]

Regulation of non-speech conduct that only incidentally burdens protected commercial speech is constitutionally permissible, however. Thus, for example, a provision of the Federal Food, Drug, and Cosmetic Act prohibiting interstate shipment of drugs that are subject to, but have not secured, FDA approval is permissible, even though another provision of the act defines drugs in relation to the promotional claims made about the product.

2. The First Amendment Protects Against Compelled Commercial Speech

The Supreme Court has stated that, in comparison to non-commercial protected speech, "[p]urely commercial speech is more susceptible to compelled disclosure requirements."[40] In *Zauderer v. Office of Disciplinary Counsel*,[41] a seminal case involving compelled commercial speech intended to remedy potentially misleading speech, the Supreme Court acknowledged that disclosure requirements for commercial speech, such as those involving warnings and disclaimers, may be appropriate because they "trench much more narrowly on an advertiser's interests than do flat prohibitions on speech."[42] However, the Court noted that compelled disclosure requirements do implicate advertisers' First Amendment rights and that "*unjustified* or *unduly burdensome* disclosure requirements might offend the First Amendment by chilling protected commercial speech."[43] Accordingly, the Court held that disclosure requirements must be "reasonably related" to the government's interests in preventing consumers from being deceived.[44]

A more recent Supreme Court case, *United Foods*, clarified that compelled expression is unconstitutional if it is *not necessary* to prevent consumers from being deceived.[45] In that case, the Court found that an assessment imposed on a mushroom producer, to pay for ads by others promoting mushroom sales, was not permitted under the First Amendment. The Court concluded that its holding was consistent with *Zauderer* because the assessment was not necessary to make voluntary ads "nonmisleading for consumers."[46]

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[39] *Id.* at 597 (citation omitted).

[40] *Riley v. National Fed'n of the Blind*, 487 U.S. 781, 796 n.9 (1988); *Virginia Bd. of Pharmacy*, 425 U.S. at 771 n. 24.

[41] 471 U.S. 626, 651 (1985).

[42] *Id.*

[43] *Id.* (emphasis added).

[44] *See id.*

[45] *United Foods*, 533 U.S. at 416.

[46] *Id.*

C. Identifying Permissible Infringements on Protected Commercial Speech

1. The *Central Hudson* Test

To identify regulations that unconstitutionally abridge commercial speech rights, the Supreme Court established a four-step test. This test, first articulated in *Central Hudson*, first asks whether the commercial speech at issue involves unlawful activity, or whether it is misleading.[47] If so, there is no need to proceed to the remaining steps because the speech would not be protected under the First Amendment. However, if the speech concerns lawful activity and is not misleading, courts must ask the following sequence of questions: whether the asserted government interest is substantial; whether the regulatory policy directly and materially advances the governmental interest asserted; and whether the regulatory policy is no more extensive than necessary to serve the government's asserted interest.[48] The last three inquiries "must be answered in the affirmative for [government activity] to be found constitutional."[49] Importantly, it is well-established that "the party seeking to uphold a restriction on commercial speech carries the burden of justifying it."[50]

a. *Central Hudson* Prong 1: The Government Must Establish that the Commercial Speech at Issue Involves Unlawful Activity or Is Misleading.

The first inquiry under the *Central Hudson* test is whether the commercial speech at issue involves unlawful activity, or is misleading. In most commercial speech cases, this issue is not in controversy and courts simply proceed to the remaining three steps.[51] In fact, the court need not definitively determine that the commercial speech at issue is not misleading, before proceeding to the remaining three steps under *Central Hudson*. According to the Supreme Court in *In re R.M.J.*:[52]

> Truthful advertising related to lawful activities is entitled to the protections of the First Amendment. But when the particular content or method of the advertising suggests that it is inherently misleading or when experience has proved that in fact such advertising is subject to abuse, the States may impose appropriate restrictions. [Inherently] misleading advertising may be prohibited entirely. But the States may not place an absolute prohibition on . . . potentially misleading

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[47] *See Central Hudson* at 566.

[48] *See Western States*, 122 S. Ct. at 1504 (articulating the *Central Hudson* test); *Edenfield*, 507 U.S. at 770-71 (noting that under the third prong, the government must demonstrate that its restriction directly advances its interests to a *material* degree); *Lorillard Tobacco*, 533 U.S. at 555 (same). Notably, in his concurring opinion in *Western States*, Justice Thomas suggested that a more rigorous standard than *Central Hudson* should be applied in commercial speech cases where the asserted government interest is achieved by keeping the public in the dark. *See id.* at 1509 (Thomas, J., concurring) (citing *44 Liquormart*, 517 U.S. at 523).

[49] *Id.*

[50] *Edenfield*, 507 U.S. at 770 (*quoting Bolger*, 463 U.S. at 71, n. 20).

[51] *See, e.g., Western* States, 122 S. Ct. at 1504.

[52] *In re R.M.J.*, 455 U.S. 191, 203 (1982).

> information . . . if the information also may be presented in a way that is not deceptive.[53]

In other words, if the court finds that the commercial speech at issue is inherently misleading, the inquiry will be over, but if the court finds that the advertising is only potentially misleading, the analysis under *Central Hudson* will continue.

Courts are generally disinclined to find advertisements inherently misleading, particularly if the government's argument is based simply on a paternalistic assumption that consumers are not sophisticated enough to discern the true meaning of a claim.[54] For example, the D.C. Circuit, in *Pearson v. Shalala*,[55] characterized the government's argument – that certain health claims for dietary supplements were inherently misleading – as "almost frivolous."[56]

Nevertheless, the court in *Pearson* did not rule out the possibility that a claim may be deemed inherently misleading, such that it would be incurable by a disclaimer, if: (1) the evidence substantiating an express health claim were "outweighed by evidence against the claim," (2) the "evidence in support of a claim [were] qualitatively weaker than evidence against the claim – for example, where the claim rests on only one or two old studies," or (3) empirical evidence indicates that disclaimers will "bewilder" consumers.[57]

b. *Central Hudson* Prong 2: The Government Must Establish that Its Asserted Interest Is Substantial.

The second inquiry under the *Central Hudson* test requires the government to establish a "substantial" non-speech interest to justify its action.[58] Courts have repeatedly recognized as substantial, the

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[53] *Id.* (emphasis added).

[54] *See id.*

[55] 164 F.3d 650 (D.C. Cir. 1999).

[56] *Id.* at 655 (ultimately finding that the government, under *Central Hudson*, was required to consider whether the inclusion of appropriate disclaimers would negate the potentially misleading nature of the health claims). The court explained that the government essentially had argued that the health claims were inherently misleading because "they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment . . . as if the consumers were asked to buy something while hypnotized." *Id. See also Peel v. Attorney & Disciplinary Comm'n*, 496 U.S. 91, 105 (1990) (similarly rejecting a paternalistic assumption that the recipients of letterhead are "no more discriminating than the audience for children's television).

[57] *Pearson*, 164 F.3d at 659-60. Notably, in *Pearson*, the court ultimately proceeded to the remaining three steps in the *Central Hudson* test because it agreed with the government that the claims were, at minimum, "potentially" misleading. *See id.* at 655.

[58] *Western States* 122 S. Ct. at 1504 (citing *Central Hudson*, 447 U.S. at 566).

interest of "promoting the health, safety, and welfare" of citizens[59] and the interest of ensuring that consumers are not misled.[60]

Notably, however, the Supreme Court has rejected the notion that government paternalism, alone, will satisfy this requirement. As early as 1977, the Supreme Court in *Bates v. State Bar of Arizona*,[61] noted that it "view[s] as dubious any justification" for a restriction on commercial speech "that is based on the benefits of public ignorance."[62] Similarly, just this term, the Court flatly rejected the notion that advertising compounded drugs would cause patients to talk doctors into prescribing unnecessary drugs because it merely "amount[ed] to a fear that people would make bad decisions if given truthful information,"[63] noting that the "First Amendment directs the [Court] to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."[64]

c. *Central Hudson* Prong 3: The Government Must Establish that Its Regulatory Policy Directly and Materially Advances Its Asserted Interest.

The third inquiry under the *Central Hudson* test asks whether the regulatory policy directly advances the governmental interest asserted.[65] As mentioned, the government has the burden of demonstrating that this step is met.[66] "This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a *material* degree."[67] As the Court clarified in *Ibanez v. Florida Department of Business & Professional Regulation*,[68] if the commercial speech doctrine is to retain its force, the Court "cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden . . . ."[69] Moreover, a restriction cannot "be sustained if it provides only ineffective or remote support for the

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[59] *See, e.g., Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995); *Pearson*, 164 F.3d at 655.

[60] *Edenfield*, 507 U.S. at 769 ("[T]here is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial"); *Pearson*, 164 F.3d at 655.

[61] 433 U.S. 350, 375 (1977).

[62] *Id.*

[63] *Western States*, 122 S. Ct. at 1507.

[64] *Id.* at 1508 (citing *44 Liquormart*, 517 U.S. at 503).

[65] *See id.* at 1504.

[66] *See, e.g., Edenfield*, 507 U.S. at 770.

[67] *Lorillard Tobacco*, 533 U.S. at 555 (quoting *Edenfield*, 507 U.S. at 770-71).

[68] 512 U.S. 136, 146 (1994) (quotations omitted).

[69] *Id.*

government's purpose,"[70] nor can it be upheld if there is "little chance that the restriction will advance a legitimate goal."[71]

Edenfield stands for the proposition that the government needs evidence to demonstrate that a restraint on commercial speech directly and materially advances its interests.[72] There, the Supreme Court held that the ends sought by the Florida Board of Accountancy's ban on in-person solicitation by accountants (*i.e.*, to prevent consumer fraud and overreaching and to preserve the independence of accountants) were not advanced by the ban because the Board failed to submit any studies or anecdotal evidence suggesting that it did. Rather, the Board merely submitted an affidavit, which contained "nothing more than a series of conclusory statements that add[ed] little if anything to the Board's original statement of justifications," and a report, which in fact contradicted the Board's assertion that lifting the ban would compromise the independence of accountants.[73] Moreover, other literature on the accounting profession belied the Board's concerns.[74]

d. *Central Hudson* Prong 4: The Government Must Demonstrate that Its Regulatory Policy Is No More Restrictive of Speech than Necessary to Advance Its Asserted Interest.

The fourth inquiry under the *Central Hudson* test compliments the third and asks whether the regulatory policy is more extensive than necessary to serve the government's asserted interest.[75] As the Supreme Court in *Western States* recently clarified, under this prong of *Central Hudson*, "if the Government could achieve its interests in a manner that does not restrict speech, or restricts less speech, the Government must do so."[76] The Court explained that "[i]f the First Amendment means anything, it means that regulating speech must be a last – not first – resort."[77]

Notably, these statements, which were made in April of this year, reaffirm the Court's retreat from its holding in *Posados de Puerto Rico Ass'n v. Tourism Co.*[78] *Posados* suggested that the "fit" between the legislative means and the end need only be "reasonable" and that deference to the legislature in these matters is appropriate. However, the Court, in *44 Liquormart*, declared that "*Posados* clearly erred in

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[70] *Edenfield*, 507 U.S. at 770-771.

[71] *Greater New Orleans Broad. Ass'n*, 527 U.S. at 193.

[72] *See Edenfield*, 507 U.S. at 777.

[73] *Id.* at 771.

[74] *See id.* at 772.

[75] *See Western States*, 122 S. Ct. at 1504.

[76] *Id.* at 1506.

[77] *Id.* at 1507.

[78] 478 U.S. 328 (1986). *See also Board of Trustees v. Fox*, 492 U.S. 469 (1989).

concluding that it was 'up to the legislature' to choose suppression over a less restrictive speech policy."[79]

The Court in *44 Liquormart* invalidated a law prohibiting price advertising of liquor, in part, because of the availability of alternatives to advance the government's stated interest of reducing alcohol consumption, such as direct regulation or taxation to elevate prices, or per capita purchase limits.[80] In addition, where the use of a disclaimer is an alternative to outright suppression, the Supreme Court, in *Bates* and *Peel v. Attorney Registration & Disciplinary Commission*, has made it clear that disclaimers are constitutionally preferable.[81]

It should be noted that the government's evidentiary burden is just as great at this final stage of the *Central Hudson* analysis as it is at earlier stages.[82] Moreover, the court in *Pearson* suggested a preference for a showing by the government of "empirical evidence" to support its burden under prong four.[83]

2. There Exists a Presumption Against the Constitutionality of Prior Restraints on Commercial Speech.

The essence of a prior restraint is that it gives "public officials the power to deny use of a forum in advance of actual expression."[84] For instance, pre-approval schemes that require application to a regulatory entity for permission to make certain claims are illustrative of classic prior restraints. Prior restraints are the most serious and least tolerable infringement on First Amendment rights.[85] Although prior restraints are not *per se* unlawful, there is a heavy presumption against their

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[79] *44 Liquormart*, 517 U.S. at 509-10.

[80] *See id.* at 507; *see also Western States*, 122 S. Ct. at 1506-07 (finding that the law prohibiting the advertising and promotion of compounded drugs was unconstitutional because there were multiple other means by which the government could have advanced its interests, without infringing on First Amendment rights).

[81] *See, e.g., Peel v. Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 110 (1990) ("To the extent that potentially misleading statements of private certification or specialization could confuse consumers, a State might consider screening certifying organizations or requiring a disclaimer about the certifying organization or the standards of a specialty. A State may not, however, completely ban statements that are not actually or inherently misleading"); *Bates*, 433 U.S. at 376 (holding that "incomplete" attorney advertising was not inherently misleading and that "the preferred remedy is more disclosure, rather than less"); *Pearson*, 164 F.3d at 655–60 (citing *Bates* and *Peel* for these propositions and holding that the FDA was required to consider whether the inclusion of disclaimers would negate the potentially misleading nature of the claims at issue). *But cf. Friedman v. Rogers*, 440 U.S. 1, 15-16 (1979) ("[T]here is no First Amendment rule . . . requiring a State to allow deceptive or misleading commercial speech whenever the publication of additional information can clarify or offset the effects of spurious communication."). Importantly, the D.C. Circuit has stemmed any argument that could be raised that the constitutional preference for disclaimers is weakened by *Friedman v. Rogers*. According to the D.C. Circuit, *Friedman* itself limits its holding to the special status of trade names. *See Pearson*, 164 F.3d at 657.

[82] *See Pearson*, 164 F.3d at 659 n.9.

[83] *See id.* at 659-60 (appearing to suggest that the government must provide empirical evidence to demonstrate that a disclaimer would be insufficient to advance its interest in preventing deception without bewildering consumers).

[84] *Southeastern Promotions*, 420 U.S. at 558-59.

[85] *See Nebraska Press Ass'n v. Stuart*, 427 U.S. 539, 559 (1976).

constitutionality.[86] The Supreme Court, in *Southeastern Promotions Ltd. v. Conrad*, a seminal case on prior restraint, explained:

> "The presumption against prior restraints is heavier – and the degree of protection broader – than that against limits on expression imposed by criminal penalties. Behind the distinction is a theory deeply etched in our law: a free society prefers to punish the few who abuse the rights of speech after they break the law than to throttle them and all others beforehand. It is always difficult to know in advance what an individual will say, and the line between legitimate and illegitimate speech is so finely drawn that the risks of freewheeling censorship are formidable.[87]

According to *Southeastern Promotions*, a prior restraint under the Federal Food, Drug and Cosmetic Act[88] may be deemed lawful only if FDA demonstrates that it: (1) "fit[s] within one of the narrowly defined exceptions to the prohibition against prior restraints," and (2) "ha[s] been accomplished with procedural safeguards that reduce the danger of suppressing constitutionally protected speech."[89]

In 1931, in *Near v. Minnesota*, the Supreme Court defined the exceptions applicable to the first prong, in dicta, simply as: (a) the protection of national security (*e.g.*, protects the publication of "the sailing dates of transports or the number or location of troops"), (b) the suppression of obscenity, and (c) the protection of the public against incitement to violence.[90] The Supreme Court has subsequently suggested that "commercial speech" may constitute a fourth exception to the first prong.[91] More recent decisions, however, have rejected that proposition, finding that prior restraints on commercial speech, at minimum, must have the requisite procedural safeguards required by the second prong.[92]

Notably, even in cases where the government claims that one of the narrow exceptions identified under the first prong has been met, Professor Laurence H. Tribe has observed that a prior restraint cannot be justified unless "the expected loss from impeding speech in advance is minimized by the

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[86] *See Southeastern Promotions*, 420 U.S. at 558-59.

[87] *Id. See also Organization for a Better Austin v. Keefe*, 402 U.S. 415 (1971) (noting that the government "carries a heavy burden of justification for the imposition" of prior restraints on commercial speech).

[88] *See generally* 21 U.S.C. § 321 *et seq.* (Supp. 2002).

[89] *Southeastern Promotions*, 420 U.S. at 559.

[90] *See Near v. Minnesota*, 283 U.S. 697, 716 (1931).

[91] *See Central Hudson.*, 447 U.S. at 571; *Virginia State Bd. of Pharmacy*, 425 U.S. at 772.

[92] *See New York Magazine v. Metropolitan Transit Auth.*, 136 F.3d 123, 131 (2d Cir. 1998) ("[a]lthough the Supreme Court has indicated that commercial speech may qualify as one of the exceptions to the bar on prior restraints, we see no reason why the requirement of procedural safeguards should be relaxed whether speech is commercial or not") (emphasis added); *see also In re Search of Kitty's East*, 905 F.2d 1367, 1371 (1990) (recognizing that the Supreme Court "has not distinguished between political and commercial speech when it has held that any prior restraint must be followed by prompt judicial review").

unusual clarity of the prepublication showing of harm."[93] Professor Tribe's observation was based, in part, on concurring opinions, in the *per curiam* decision *New York Times Co. v. United States*,[94] and its progeny. In *New York Times Co.*, three Justices found that the government's attempt to enjoin newspapers from publishing historical documents regarding Viet Nam policy was unconstitutional because the government failed to allege or present evidence that the speech would "inevitably, directly, and immediately" cause irreparable harm.[95]

Under the second prong, to overcome the heavy presumption against the constitutionality of prior restraints, the government also must show that any restraint contains all of the following procedural safeguards: (1) the prior restraint must operate such that the censor bears the burden of instituting a judicial proceeding to prove that the material at issue is not protected by the First Amendment; (2) the prior restraint must be imposed only for a short period of time and only for the purpose of maintaining the status quo; and (3) the prior restraint must assure a prompt final judicial determination.[96]

III. Overview of Recent First Amendment Case Law

A. The Federal Food, Drug, and Cosmetic Act Is a Claims-Based Statute

The Federal Food, Drug, and Cosmetic Act,[97] the statute from which FDA's authority to regulate foods, drugs, medical devices, and cosmetics principally, defines the terms "drug" and "device" relative to the uses for which they are promoted.[98] Consequently, courts have held, for example, that "regardless of the actual physical effect of a product, it will be deemed a drug for purposes of the [Federal Food, Drug, and Cosmetic Act] where the labeling and promotional claims show intended uses that bring it within the drug definition."[99] The promotional and labeling claims that bring a product under FDA's jurisdiction are, of course, conveyed by speech. Thus, the constitutional protections for commercial speech are closely intertwined with FDA's core jurisdiction over regulated products.

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[93] Laurence H. Tribe, *American Constitutional Law*, § 12-36 (2d. 1988).

[94] *New York Times Co. v. United States*, 403 U.S. 713, 726-27 (1971) (per curiam).

[95] *See id.* at 726-27 (Brennan, J., concurring); *see id.* at 730 (Stewart, J. and White, J., concurring) (similarly noting that disclosure would not "surely result in direct, immediate, and irreparable damage to our Nation or its people"); *see, e.g., In re Providence Journal Co.*, 820 F.2d 1342, 1350-51 (1st Cir. 1986) (citing *New York Times Co.* for this proposition and finding the prior restraint at issue unconstitutional); *Beckerman v. City of Tupelo*, 664 F.2d 502, 514 (5th Cir. 1981); *Bernstein v. United States*, 945 F. Supp. 1279, 1288 (N.D. Cal. 1996).

[96] *See Southeastern Promotions*, 420 U.S. at 560 (citing *Freedman v. Maryland*, 380 U.S. 51, 58 (1965)).

[97] 21 U.S.C. § 321 *et seq.* (Supp. 2002).

[98] *See id.* § 321(g)(1), (h) (defining the term "drug" and the term "device," respectively).

[99] *United States v. Article . . . Consisting of 216 Cartoned Bottles*, 409 F.2d 734, 739 (2d Cir. 1969).

B. Overview of Recent FDA First Amendment Litigation

Several recent cases – *Washington Legal Foundation, Pearson, and Western States* – have called into question FDA regulatory policies affecting commercial speech. Although *Washington Legal Foundation* involved FDA's policies for manufacturer communications to physicians regarding off-label uses, rather than advertising issues that more directly affect FAC's constituency, a summary of that case, is provided below because each of the three cases are recent victories for free speech. The cases together are illustrative of a judicial trend to enjoin FDA from implementing policies that restrict more commercial speech than necessary. Moreover, as a general rule, if FDA impermissibly restricts commercial speech in one context, such as manufacturer communications to physicians, it will have a broad chilling effect on the commercial speech of the entire regulated community.

1. *Washington Legal Foundation v. Henney*

Although this case was brought to vindicate First Amendment rights, and the trial court relied on the First Amendment in its judgment, the appellate court's ruling in *Washington Legal Foundation v. Henney*[100] was actually based upon statutory interpretation. This case involved a suit brought by the Washington Legal Foundation ("WLF"), which claimed that FDA had violated its physician members' First Amendment right to receive information about off-label uses of drugs and medical devices. Specifically, WLF challenged provisions of FDA Guidance documents that imposed limitations on drug and device manufacturers' distribution of independent medical and scientific publications to physicians ("enduring materials")[101] and contributions to physician-targeted, continuing medical education ("CME") programs[102] regarding off-label uses of their products.

Applying *Central Hudson*, the district court recognized the government's substantial interest in encouraging manufacturers to seek FDA approval for off-label uses of their products, under the second prong of the test, and found that the FDA guidance documents directly advanced that interest, under the third prong. Ultimately, however, the trial court held the documents to be unconstitutional under the test's fourth prong because they sought to restrict significantly more speech than necessary to achieve their goal.[103]

Subsequent to the trial court's decision, the Food and Drug Administration Modernization Act of 1997 ("FDAMA")[104] became effective. FDAMA, which superceded the FDA guidance documents,

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[100] 202 F.3d 331 (D.C. Cir. 2000).

[101] For example, pursuant to one of the so-called "enduring materials" guidances, manufacturers could refer to a product's off-label uses, however, " the principal subject of the article *should* be the use[] . . . that has been approved by FDA." *Guidance for Industry Funded Dissemination of Reference Texts*, 61 Fed. Reg. 52,800, 52801 (1996) (emphasis added).

[102] The CME Guidance announced 12 factors that would be considered by FDA when determining whether a CME program is independent of manufacturer influence. *See Guidance for Industry: Industry-Supported Scientific and Educational Activities*, 62 Fed. Reg. 64,093 (1997).

[103] *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998).

[104] Pub. L. No. 105-115, 111 Stat. 2296 (1997).

established the same underlying policies that the court had invalidated. Consequently, the trial court issued a subsequent opinion in which the FDAMA provisions were also held unconstitutional.[105]

On appeal to the D.C. Circuit, however, FDA stipulated that neither FDAMA nor any other statute authorized it to regulate the speech at issue. Instead, FDAMA merely offered those complying with the "voluntary" guidelines safe harbor from having the distribution of enduring materials and CME content suggestions used as evidence in any enforcement action that may be brought with regard to violation of applicable "misbranding" or "intended use" statutory or regulatory provisions.

Ruling FDA's stipulation to be "nothing less than an official interpretation of the FDAMA which the agency may not change unless it provides a reasoned explanation for doing so," the court held that FDA lacked authority to impose the commercial speech restraints it had defended at trial.[106] Finding that no constitutional controversy survived, the trial court's invalidation of FDAMA was vacated and the case was dismissed.

Ultimately, *Washington Legal Foundation* clarified FDA's lack of statutory authority to regulate the distribution of enduring materials and contributions toward CME programs pertaining to off-label uses of drugs. However, the trial court's First Amendment analysis of FDA restraints on the commercial speech rights of drug and device manufacturers, although vacated on other grounds, is consistent with a judicial trend, exemplified by *Pearson* and *Western States* (summarized below), to enjoin FDA from implementing policies that restrict more commercial speech than necessary.

2. *Pearson v. Shalala*

In *Pearson v. Shalala*,[107] the D.C. Circuit held that FDA's unwillingness to approve dietary supplement health claims on product labels, absent "significant scientific agreement," violated the First Amendment. The court ruled that FDA must consider whether the inclusion of appropriate disclaimers would remedy the potentially misleading nature of a health claim that falls short of the standard.

In that case, FDA asserted that "health claims lacking 'significant scientific agreement' are *inherently* misleading and thus entirely outside the protection of the First Amendment,"[108] or alternatively, "at least potentially misleading."[109] The court characterized the government's assertion that such claims are inherently misleading as "almost frivolous," stating that it was not as if the health claims had "such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment . . . as if the consumers were asked to buy something while hypnotized."[110]

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[105] *See Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999).

[106] *Washington Legal Found.*, 202 F.3d at 336.

[107] 164 F.3d 650 (D.C. Cir. 1999).

[108] *Id.* at 655 (emphasis in original).

[109] *Id.*

[110] *Id.*

Finding that health claims that lack "significant scientific agreement," are at most "potentially misleading," the court proceeded to the remaining three prongs of the *Central Hudson* test. Under the second prong, the court concluded that the government's asserted interests (*i.e.*, "the protection of public health and prevention of consumer fraud") were substantial.[111] However, the court ruled that FDA failed the third prong because its interest in protecting public health was not directly advanced by FDA's ban on unapproved health claims. The court explained that FDA had neither claimed nor established that the products were unsafe. The court also held that FDA failed the fourth prong because FDA's unwillingness to consider the use of disclaimers to cure potentially misleading claims did not reasonably fit the agency's goal of preventing consumer fraud. Reversing the lower court's decision, the appellate court remanded to the trial court with instructions to subsequently remand to FDA "to draft precise disclaimers for each of the appellants' four claims."[112]

3. *Thompson v. Western States Medical Center*

Thompson v. Western States Medical Center[113] involved an effort by a group of pharmacists specializing in the compounding of drugs to secure an injunction against enforcement of provisions of FDAMA restricting advertising of compounded drug products. The challenged provisions exempted compounded drugs from the Federal Food, Drug and Cosmetic Act's "new drug" and other requirements so long as, *inter alia*, the pharmacists did not advertise or promote them. Under FDAMA, any pharmacist advertising a compounded drug product without first securing new drug approval for the product was subject to an enforcement action by FDA. The pharmacists asserted that this advertising prohibition constituted an abridgement of their First Amendment rights to free speech. Both the federal trial court and Ninth Circuit had agreed.

The government did not contest that the challenged FDAMA provisions restricted commercial speech; nor did it assert that the targeted speech involved illegal activity or was misleading.[114] Instead, the government claimed that it aimed to prohibit the large scale manufacturing and sales of compounded drugs and that advertising of such products was a "fair proxy for actual or intended large-scale manufacturing."[115] Therefore, the government believed that by banning solicitation and advertising, it could effectively prevent mass manufacturing of these products.

Applying *Central Hudson*, the Court found the government's asserted interests to be substantial, under prong two, and acknowledged that FDAMA's commercial speech restrictions *might* directly advance these interests, under prong three. However, the Court ultimately affirmed the lower courts' injunction because the government "failed to demonstrate that the speech restrictions are 'not more extensive than is necessary to serve [those] interest[s],"[116] thus failing to satisfy prong four.

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[111] *Id.* at 655-56.

[112] *Id.* at 659.

[113] 122 S. Ct. 1497 (2002).

[114] Thus, the government effectively stipulated to satisfaction of the first prong of the *Central Hudson* test.

[115] *Western States*, 122 S. Ct. at 1505.

[116] *Id.* at 1506 (quoting *Central Hudson*, 447 U.S. at 566).

The Court suggested several means by which the government might have pursued its asserted interests without so dramatically restricting protected speech, noting that the government had failed to explain why these alternatives were insufficient.[117] The Court, in fact, chastised the government for offering no hint that it had even considered any alternatives to the harsh prohibition it chose.

Importantly, the Court found that, even if the government had asserted an interest in preventing misleading advertisements and could show that the advertisements were potentially misleading, "this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown."[118] Moreover, the Court added that the amount of beneficial speech prohibited by FDAMA provided an additional basis for invalidating the act.[119]

Western States' most important contribution is its clarification of the scope of the analysis conducted pursuant to the fourth prong of the *Central Hudson* test. Thus, the government may not prohibit commercial speech, even where doing so directly advances the substantial interest it asserts, unless it can prove that the use of warning labels, or other less speech restrictive policies, would be inadequate.

IV. Role and Validation of Disclaimers, Qualifying Information and Warnings

As discussed above, the case law following *Central Hudson* instructs that disclaimers are "constitutionally preferable to outright suppression."[120] As noted, in *Pearson*, the D.C. Circuit held that FDA could not restrict health claims on dietary supplement labels unless it could prove that the addition of disclaimers and qualifying information would be insufficient to advance its substantial interest in preventing consumer confusion.[121] Similarly, *Western States* made it clear that disclaimers are constitutionally preferable to suppression in the context of drug advertising.[122]

Although FAC agrees with these holdings, it cautions that they do not give FDA unbridled discretion to require disclaimers, qualifying information, and warnings. As the holding in *United Foods*, instructs – compelled speech that is unnecessary to prevent consumers from being misled is unconstitutional.[123] This principle is important in the context of prescription drug advertising,

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[117] The Court reminded the government that it carried the burden of justifying the restriction it sought to impose. *Id.* at 1507 (citing *Edenfield*, 507 U.S. at 770).

[118] *Id.* at 1508.

[119] *Id.* at 1509 ("The fact that the FDAMA would prohibit such seemingly useful speech even though doing so does not appear to directly further any asserted governmental objective confirms our belief that the prohibition is unconstitutional.").

[120] *See, e.g.*, *Pearson*, 164 F.3d at 657 (citing *Peel*, 496 U.S. at 110; *R.M.J.*, 455 U.S. at 206; *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 478 (1988)).

[121] *See id.* at 655-60.

[122] *See Western States*, 122 S. Ct. at 1508.

[123] *See United Foods*, 533 U.S. at 416.

particularly since the labeling for the product is the last resource and adequately lists the associated risks.

As detailed in Section VII(A), the Federal, Food, Drug, and Cosmetic Act, and its implementing regulations, require print advertising to include a *brief summary* of information related to side effects, contraindications, and effectiveness, and broadcast advertising to disclose *major risks* and make *adequate provision* for the dissemination of more detailed labeling.[124] To the extent that these safety disclosures are *necessary* to prevent the ads from being misleading, they are consistent with the First Amendment, under *United Foods*. However, in some instances, FDA's advertising policies require excessive disclosure information, for example, some of the information contained in the *brief summary*. Shortening the *brief summary* and sharpening its focus would better convey key information and would prevent consumers from ignoring lengthy disclosures altogether.

FDA should carefully scrutinize its policies for print and broadcast prescription drug advertising, which compel disclaimers, qualifying information, and warnings, as well as its other policies that compel speech, to ensure that they pass constitutional muster.

V. FDA Must Apply All Provisions of the Federal Food, Drug, and Cosmetic Act In Accordance with First Amendment Jurisprudence, Regardless of the Product Category Implicated.

The first question in FDA's request for comments asks: (1) whether speech about drugs should be regulated more comprehensively than speech about dietary supplements (or any other FDA-regulated product), and what type of record evidence it would take to sustain such a position, (2) whether FDA could sustain a position that certain promotional speech about drugs is inherently misleading, unless it complies with FDA requirements, and (3) whether the answers to the first two inquiries turn on whether the speech is directed at learned intermediaries or consumers. FAC's responses to those questions follow.

A. Speech About One FDA-Regulated Product Category Cannot Presumptively Be Regulated More Comprehensively than Speech About Another, Across the Board, Without Violating the First Amendment.

There are no legal presumptions in the First Amendment jurisprudence that make it more likely that a court will uphold commercial speech restrictions when a certain class of FDA-regulated products – such as prescription drugs – is involved. For example, *Central Hudson* requires that FDA's chosen regulatory policies directly and materially advance a substantial interest in a manner that does not restrict more speech than necessary to achieve that interest – no matter the product category.[125] Courts are obligated to apply this test in the same manner, regardless of whether the FDA policy at issue involves drugs, conventional foods, dietary supplements, medical devices, or cosmetics. That said, the nature of the product category at issue may have some bearing on the outcome of the First Amendment analysis.

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[124] *See* 21 U.S.C. § 352(n) (Supp. 2002); 21 C.F.R. § 202.1(e) (2002); *see also* Guidance for Industry: Consumer-Directed Broadcast Advertisements, FDA, www.fda.gov/cder/guidance /1804fnl.htm; Draft Guidance for Industry, Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements, FDA, www.fda.gov/cber/gdlns/consumed.htm.

[125] *See Western States*, 122 S. Ct. at 1504 (citing *Central Hudson*); *Edenfield*, 507 U.S. at 770-71.

Nowhere is the consistency of the application of *Central Hudson* across regulated-product lines more apparent than in *Western States*, which involved ads for compounded drugs, and *Pearson*, which involved claims for dietary supplements. In those cases, the Supreme Court and the D.C. Circuit, respectively, concluded that disclaimers are preferable to suppression where disclaimers can remedy the potentially misleading nature of speech.[126] Accordingly, it is clear that this principle should apply to all regulated-products, particularly where the regulatory regimes are not materially different, as with conventional foods and dietary supplements.[127]

B. FDA Cannot Sustain a Position that Certain Promotional Speech About Drugs Is Inherently Misleading Unless the Speech Complies with FDA Requirements.

In the context of *Central Hudson*, the Supreme Court, in *In re R.M.J.*,[128] has already distinguished "inherently misleading" speech from "potentially misleading" speech, explaining that speech is only "potentially misleading" if the speech may be presented in a way that is not deceptive.[129] The D.C. Circuit, in *Pearson*, has taken this a step further, noting that "inherently misleading speech" exists if: (1) the evidence substantiating the express claim is "outweighed by evidence against the claim," (2) if the "evidence in support of a claim [is] qualitatively weaker than evidence against the claim – for example, where the claim rests on only one or two old studies," or (3) if empirical evidence indicates that disclaimers will "bewilder" consumers.[130] Accordingly, any attempt by FDA to define promotional speech about drugs as "inherently misleading," which does not fall into one of the *Pearson* categories or that could be cured if presented differently, would be highly suspect. Moreover, such an attempt would fly in the face of *Western States* and *Pearson*, which stand for the proposition that the use of disclaimers to remedy potentially misleading speech is constitutionally preferable to outright suppression.[131]

In addition, any regulatory scheme that would permit FDA to deem certain promotional speech about drugs inherently misleading, absent compliance with FDA requirements, would give FDA unbridled discretion to proscribe speech, before the words were even formed – and thus, would operate as a prior restraint. Indeed, the essence of a prior restraint is that it gives "public officials the power to deny use of a forum in advance of actual expression."[132] As mentioned, there is a heavy presumption against the constitutionality of prior restraints, and to justify any prior restraint, FDA would have to demonstrate that the affected speech fell within one of the narrow exceptions

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[126] *See Pearson*, 164 F.3d. at 658-59; *see also Western States*, 122 S. Ct. at 1508.

[127] *See infra*, discussion at Section VI.

[128] *In re R.M.J.*, 455 U.S. 191, 203 (1982).

[129] *See id.*; *see also Pearson*, 164 F.3d at 655 (quoting *In re R.M.J.*).

[130] *Pearson*, 164 F.3d at 659-60.

[131] *See id.* at 658-59; *see also Western States*, 122 S. Ct. at 1508.

[132] *Southeastern Promotions*, 420 U.S. at 558-59.

to the prior restraint doctrine, and that the prior restraint contained the requisite procedural safeguards.[133]

C. Neither Conclusion Above Necessarily Turns Solely on Whether Speech Is Directed at Consumers or Learned Intermediaries.

As demonstrated above, speech about one FDA-regulated product category cannot be regulated more comprehensively than speech about another, across the board, without violating the First Amendment, and FDA cannot sustain a position that certain promotional speech about drugs is inherently misleading absent compliance with FDA requirements.

These determinations do not necessarily turn solely on whether the speech is directed at consumers or learned intermediaries. A prior restraint that would give FDA the power to deny speech concerning drugs (or any other product) in advance of actual expression would be constitutionally suspect regardless of the targeted audience.[134] FDA must justify any prior restraint on a case-by-case basis. Similarly, under *Central Hudson* and *Western States*, FDA must demonstrate on a case-by-case basis that any general restriction on speech involving drugs (or any other product) directly and materially advances FDA's interests and is no more extensive than necessary, regardless of the audience targeted by the restricted speech.[135]

Notably, FDA's regulatory schemes for prescription drug and "restricted device" advertising, for the most part, impose fundamentally the same requirements on ads directed towards consumers as those directed towards learned intermediaries. FDA's labeling requirements for prescription drugs and "restricted devices" are extensive.[136] Even FDA's less restrictive requirements for ads mandate that: (1) print ads for prescription drugs include a *brief summary* of information from the product's approved package labeling; (2) broadcast ads for drugs disclose the *major risks*,[137] and make *adequate provision* for the "dissemination of the approved or permitted package labeling in connection with the broadcast presentation;"[138] and (3) ads for "restricted devices" contain a brief summary statement of the devices' intended uses and relevant warnings, precautions, side-effects, and indications.[139] Notably, however, FDA generally requires that consumer-directed print advertisements and

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[133] *See id.*

[134] *Accord Southeastern Promotions Ltd. v. Conrad*, 420 U.S. 546, 558-59 (1975).

[135] *See Western States*, 122 S. Ct. at 1504 (reconfirming application of *Central Hudson*); *see also Lorillard Tobacco*, 533 U.S. at 555 (quoting *Edenfield* for the proposition that, under the third prong, the government must show that its policy directly advances its interests to a *material* degree).

[136] *See* 21 C.F.R. pts. 201, 801.

[137] *See id.* § 202.1(e)(1) (Supp. 2001) (emphasis added).

[138] *Id.* (emphasis added).

[139] 21 U.S.C. § 352(q), (r) (Supp. 2002).

broadcast advertisements communicate all relevant information in consumer-friendly language.[140] Thus, ads give learned intermediaries and consumers, alike, access to information about the risks of a product, as well as the benefits.

The Federal Trade Commission's (the "FTC's") regulatory scheme for dietary supplement ads, as well as the other named products, is less detailed and focuses on ensuring that ads for these products are not deceptive (*i.e.* false or misleading),[141] are not unfair,[142] and are adequately substantiated.[143] However, the FTC scheme, like FDA's schemes for prescription drugs and "restricted devices," requires that: (1) ads include relevant health and safety risks,[144] and (2) ads are written in language that can be easily understood by the targeted audience, whether that be consumers or learned intermediaries.[145] Notably, the labeling requirements for dietary supplements and the other named products are even more extensive.

FDA's advertising framework for prescription drugs and "restricted devices" and FTC's advertising framework for other FDA-regulated products (both of which are less comprehensive than the labeling schemes) ensure that information about potential risks associated with a product are communicated to the consumer. Accordingly, any additional requirements imposed by FDA would be more extensive than necessary, in violation of the First Amendment under *Central Hudson* and its progeny.[146]

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[140] Guidance for Industry: Consumer-Directed Broadcast Advertisements, FDA, www.fda.gov/cder/guidance /1804fnl.htm; Draft Guidance for Industry, Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements, FDA, www.fda.gov/cber/gdlns/consumed.htm.

[141] 15 U.S.C. §§ 45(a)(1), 52(a), 55(a)(1) (Supp. 2002); *see also Cliffdale Ass'n. Inc.*, 103 F.T.C. 110, 176 (1984), *appending* Letter from the FTC to the Honorable John D. Dingell, Chairman, Com. on Energy and Commerce, U.S. House of Reps. (Oct. 14, 1983) [hereinafter the "FTC Deception Policy Statement"].

[142] 15 U.S.C. §45(n); *International Harvester Co.*, 104 F.T.C. 949, 1070 (1984), *appending* Letter from the FTC to Sens. Wendell Ford and John Danforth (Dec. 17, 1980) [hereinafter the "Unfairness Policy Statement"].

[143] *See* FTC Policy Statement on Advertising Substantiation, 48 Fed. Reg. 10471 (Mar. 11, 1983).

[144] FTC Deception Policy Statement, at 182-183; (misrepresentations and omissions involving health and safety are presumptively material, and therefore, likely to be deemed deceptive). The FTC's dietary supplement guide also advises that ads that make either an express or implied safety representation should include information about any significant safety risks. In fact, according to the guide, even in the absence of affirmative safety representations, advertisers may need to inform consumers of significant safety concerns relating to the use of their product. *Dietary Supplements: An Advertising Guide for Industry*, FDA (1998), at 6, http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.pdf.

[145] To be deceptive, a claim must be misleading from the perspective of a consumer acting reasonably under the circumstances. Deception Policy Statement, at 176. If an advertiser targets audiences, such as children, the elderly, the terminally ill, or physicians, the FTC would evaluate reasonableness in light of the vulnerability or the sophistication of the audience. *See id.* at 179.

[146] *See Western States*, 122 S. Ct. at 1504.

VI. Restrictions on Claims for Foods

A. Standards for Conventional Food Claims

FDA possesses primary jurisdictional authority to regulate claims made for conventional foods on product labels, while the FTC oversees such claims when they appear via advertising.[147] FDA restrictions on labeling encompass three broad categories of claims: (1) structure/function claims,[148] (2) nutrient content claims,[149] and (3) health claims.[150]

In the wake of the D.C. Circuit ruling in *Pearson v. Shalala*,[151] invalidating FDA regulatory restrictions on dietary supplement health claim labeling, conventional food health claim standards have come under increasingly intense scrutiny. This development is largely due to the fact that the standard FDA still applies to conventional foods is exactly the same "significant scientific agreement" standard that was ruled unconstitutional in *Pearson*.

FDA's insistence on treating health claims for conventional foods and dietary supplements in labeling differently could spill over into the advertising arena. Notably, the FTC has advised that its Enforcement Policy on Food Advertising, [152] governing health claims in advertising, parallels the FDA's policy for those claims under the Nutritional Labeling and Education Act of 1990 ("NLEA"),[153] to avoid consumer confusion. That policy statement makes it clear that the FTC "accord[s] great weight" to FDA determinations in the area of food and health because of FDA's scientific expertise.[154] Such reliance by FTC makes FDA's conformity with constitutional dictates all the more important since FDA's advocacy or application of a constitutionally impermissible standard may spread beyond its immediate jurisdiction, threatening greater consumer and industry confusion and requiring lengthy and expensive judicial remedies.

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[147] Working Agreement Between FTC and FDA (1971).

[148] 65 Fed. Reg. 1000, 1034 (Jan. 6, 2000) (Structure/function claims characterize the relationship of a food or food constituent to an effect on the structure or function of the body).

[149] "Nutrient content claims" are claims that characterize the level of a nutrient in a food. 21 C.F.R. § 101.69(a)(1) (2002) (defining "nutrient content claim" under the NLEA); FTC's Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28388, 28390 (June 1, 1994) (defining "nutrient content claim").

[150] "Health claims" characterize the relationship between a substance in a food product to a disease or health-related condition. 21 C.F.R. § 101.14(a)(1) (defining "health claim" under the NLEA); *see also* 59 Fed. Reg. at 28392 (defining "health claim").

[151] 164 F.3d at 650.

[152] 59 Fed. Reg. at 28388.

[153] Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. § 343(r)).

[154] FTC's Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28388 (June 1, 1994).

B. Distinctions Between Health Claims for Conventional Foods and Dietary Supplements

Although the NLEA does not define "significant scientific agreement," it requires FDA to approve a conventional food health claim only if it finds that, "based on the totality of the publicly available scientific evidence . . . that there is *significant scientific agreement* among experts . . . that the claim is supported by such evidence."[155] In the final regulations that FDA promulgated pursuant to the NLEA, the agency chose not to identify the evidentiary criteria by which it would evaluate a claim's conformity with this significant scientific agreement standard. Instead, FDA proclaimed that it would make "case-by-case determinations."[156]

In contrast to the NLEA's express provision of the standard by which health claims for *conventional foods* are to be evaluated, the statute delegated to FDA the task of establishing the standard for *dietary supplements* by regulation.[157] In response, the agency adopted the same "significant scientific agreement" standard for dietary supplements as had been provided by the NLEA for conventional foods. In so doing, FDA ensured that health claim standards for both of the food categories would be equivalent – the only difference between them being the source of their immediate derivation. FDA has since explained its adoption of the uniform standard as an attempt to both "treat all segments of the regulated food industry with fairness"[158] and avoid the "significant potential for consumer confusion" likely to ensue when exposed to health claims for substances appearing in dietary supplements, but not when appearing in conventional foods.[159]

As discussed above, in *Pearson*, the D.C. Circuit held that the First Amendment does not permit the government to rely upon the "significant scientific agreement" standard to restrict health claims for dietary supplements unless it can demonstrate that a disclaimer would not adequately advance its interest. Although the interest asserted by the government was that of preventing deception, the court made clear that this preference for disclaimers over restrictions applies broadly.

Since *Pearson*, FDA has reaffirmed that it applies the same interpretation of the term "significant scientific agreement" to both conventional foods and dietary supplements.[160] Under certain conditions, however, the agency no longer enforces the standard in relation to dietary supplements.[161]

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[155] 21 U.S.C. § 343(r)(3)(B) (Supp. 2002) (emphasis added).

[156] 58 Fed. Reg. 2478, 2504 (January 6, 1993).

[157] 21 U.S.C. § 343(r)(5)(D) (Supp. 2002).

[158] 56 Fed. Reg. at 60540 ("If dietary supplements were subject to different rules, whether with respect to the procedure for assessment of conformity with the scientific standard or to the manner in which claims are made, there is a possibility that supplements could be made to appear somehow superior to conventional foods that contain the same nutrient. Such an appearance would not only be untrue, it would be unfair to firms producing conventional foods.")

[159] *Id.*

[160] 64 Fed. Reg. 71794 (Dec. 22, 1999).

[161] 65 Fed. Reg. 59855 (Oct. 6, 2000) (announcing that FDA will not enforce the "significant scientific agreement" standard in relation to dietary supplement health claims where: (1) the health claim petition conforms to FDA

Curiously, however, such efforts to implement the *Pearson* holding, with regard to disclaimers, has been limited to dietary supplement claims. FDA has sought to justify its unwillingness to apply *Pearson* to conventional food claims by asserting that, since the "significant scientific agreement" standard for such products was derived from the NLEA, rather than the agency's own regulations, it will continue to enforce the standard until enjoined from doing so by judicial order.[162]

FDA's narrow reading of *Pearson*, however, is unwarranted and unconstitutional. *Pearson* did not turn on an issue of administrative procedure, but rather was decided based upon application of the First Amendment. Fundamental to the court's ruling was its determination that the Constitution simply does not permit the government to categorically suppress health claims unless it can establish that the use of a less restrictive alternative, such as a disclaimer, would not suffice to advance the government's asserted interest.[163] Importantly, this constitutional dictate extends, not over regulatory activities alone, but over congressional enactments as well.[164] In other words, neither the Legislative nor the Executive Branch possesses authority to ignore the Constitution. As such, the source of the "significant scientific standard" – whether it be Congress or FDA -- is immaterial. Whether embodied in a statute or regulation, the "significant scientific agreement" standard may not constitutionally be used to restrict health claims unless FDA can demonstrate that no less restrictive alternatives, such as disclaimers, would be sufficient to advance its asserted interests.

Moreover, it should be recalled that FDA initially chose to adopt the same standard for dietary supplements and conventional foods in order to promote equitable treatment of regulated product categories and to minimize the potential for consumer confusion. FDA's current disparate treatment of these food product categories clearly violates the agency's own professed policies.

Not only does FDA lack authority to violate the Constitution, to the extent possible, it has a duty to interpret laws authorizing its action in such a way as to avoid constitutional abridgements.[165] Accordingly, FDA cannot use the "significant scientific agreement" standard to block the free flow of truthful, nonmisleading speech. Overly restrictive interpretations of this standard, such as that announced for conventional foods, have a tendency to make the standard difficult, if not impossible, to meet, thereby prohibiting more truthful, nonmisleading speech than necessary, in violation of the First Amendment.

Thus, as it has done for dietary supplement claims, the agency should issue new regulations or guidances to more broadly interpret the "significant scientific agreement" standard laid out in NLEA in light of the holding in *Pearson*. Such action would permit FDA to honor the guarantees

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requirements; (2) the scientific evidence against the health claim is outweighed by the evidence supporting it; (3) neither consumer health nor safety are threatened; and (4) other generally applicable health claim requirements are satisfied).

[162] Letter from Melinda K. Plaisier (FDA) to the Honorable David M. McIntosh (U.S. House of Representatives) (May 16, 2000).

[163] *Pearson*, 164 F.3d at 658.

[164] U.S. Const. art. VI, cl. 2.

[165] *See National Labor Relations Bd. v. Catholic Bishop*, 440 U.S. 490 (1979).

recognized by the First Amendment, while relinquishing none of its power or authority to protect the health and safety of the American people.

VII. Empirical Data Shows that FDA's Regulatory Policy for Direct-To-Consumer Drug/Device Advertising Protects the Public Health and Prevents Consumers from Being Misled.

The second question in FDA's request for comments is actually a series of questions regarding whether FDA's regulatory policy for DTC advertising (*i.e.*, drug and device advertising that is directed at consumers) adequately protects the public health and prevents consumers from being misled about potential health risks associated with prescription drugs and "restricted devices." As detailed herein, FAC strongly believes that FDA's regulatory policy adequately protects the public health. However, in some instances, it compels more disclaimers, qualifying information, and warnings than necessary to prevent consumers from being misled.

Moreover, FAC believes that some of FDA's pre-approval advertising policies should be reevaluated to ensure that they cannot be characterized as *de facto* or *de jure* prior restraints. To avoid such characterization, FDA should ensure that its pre-approval processes are truly voluntary. Further, to prevent the pre-approval systems from giving FDA unbridled discretion to reject ads, in violation of advertisers' First Amendment rights, the pre-approval processes should incorporate the procedural safeguards detailed below.

A. Background: DTC Advertising

As mentioned, the Supreme Court has recognized the importance of commercial speech, noting that "it is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed."[166] Commercial speech involving health-related issues, such as DTC advertising, is particularly important because it gets essential health information to the public and forges economic democratization. Indeed, health-related ads are frequently the only way that disadvantaged sectors of the population receive key disease information or recognize that they have health-related symptoms that can be treated. Unlike the more affluent sectors of our society, the economically disadvantaged do not subscribe to health newsletters from academic institutions, research disease symptoms on the Internet, or visit health care professionals regularly. Accordingly, health-related ads have always been vital to inform the public and to encourage the public to visit health care professionals.

However, with the dramatic changes in the healthcare industry since the 1980s, getting health-related information directly to consumers has become even more important. The changes in health care, instigated by the popularity of HMOs, have been marked by: (1) cost-cutting strategies, which penalize physicians for "seeking more time and greater discretion with patients,"[167] and (2) utilization review boards, often staffed by people with less medical training than physicians, or indeed without any medical training, that second-guess physician treatment strategies in an effort to economize.[168]

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[166] *Western States*, 122 S. Ct. at 1503.

[167] *Rx for the Health Care System*, The Wall Street Journal, Oct. 8, 1998 (quoting Dr. Michael DeBakey, the director of the DeBakey Heart Center at the Baylor College of Medicine in Houston).

[168] Chad Terhune, *Bill Says Doctors Should Make Calls on HMO Denials*, The Wall Street Journal, May 3, 2000.

In response, patients have become more sophisticated and are demanding more information about their own healthcare. Patients must have information to make the most of the time that they do get with their physicians and to challenge decisions that deny or restrict treatment.

Largely as a result of FDA's innovative guidelines for broadcast advertising in 1997,[169] manufacturers and advertisers are now playing an important role in providing consumers with this information via DTC ads. Prior to the early 1980s, pharmaceutical companies disseminated product information only to health care professionals – learned intermediaries -- to pass on to patients when appropriate. DTC advertising began in the early 1980s with print advertising, but increased substantially after 1997. It is estimated that pharmaceutical companies currently dedicate well over $2 billion to DTC advertising, in the form of television and radio ads, print ads, telephone ads, direct mail, videotapes, and brochures.

Section 502(n) of the Federal Food, Drug, and Cosmetic Act,[170] and its implementing regulations,[171] establish the regulatory framework for prescription drug ads, including DTC ads. Section 502(n), among other things, requires that prescription drug ads include "information in brief summary relating to side effects, contraindications, and effectiveness."[172] The implementing regulations for that section require print ads to actually include this *brief summary*, which generally contains information from the product's approved package labeling, and they require broadcast ads to disclose the drug's *major risks*.[173] The regulations also require broadcast advertising to make "*adequate provision* . . . for dissemination of the approved or permitted package labeling in connection with the broadcast presentation."[174]

In 1999, FDA finalized a guidance document for broadcast prescription drug ads, entitled "Guidance for Industry: Consumer-Directed Broadcast Advertisements,"[175] which assists drug manufacturers in fulfilling the "adequate provision" requirement for broadcast ads. The guidance

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[169] Guidance for Industry: Consumer-Directed Broadcast Advertisements, www.fda.gov/cder/guidance/1804fnl.htm; 64 Fed. Reg. 43197 (Aug. 9, 1999) (announcing the availability of the final guidance); *see also See* 62 Fed. Reg. 43171 (Aug. 12, 1997) (announcing the availability of the draft guidance).

[170] 21 U.S.C. § 352(n) (Supp. 2002).

[171] *See* 21 C.F.R. § 202.1 (2001).

[172] 21 U.S.C. § 352(n) (Supp. 2002).

[173] *See* 21 C.F.R. § 202.1(e)(1) (2001) (emphasis added).

[174] *Id.* (emphasis added). These requirements do not apply to "reminder" ads (*i.e.*, ads that contain the name of a product and certain descriptive information, such as pricing, but not the product's indication, dosage recommendation, or claims or representations about the product) or to "help-seeking" ads (*i.e.* ads that discuss a disease condition and advise viewers to "see your doctor" for possible treatments). *See* 21 C.F.R. § 202.1(e)(2)(i) (exempting "reminder" ads); *see also* Testimony of Nancy M. Ostrove, Ph.D., Deputy Director Division of Drug Marketing, Advertising and Communications, Center for Drug Evaluation and Research, FDA, Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Senate Committee on Commerce, Science, Transportation, U.S, Senate, July 24, 2001 ("Ostrove Statement"), at 4-5 (noting that "help-seeking" ads are not considered to be drug ads because no drug is mentioned or implied) (Exh. 1).

[175] Guidance for Industry: Consumer-Directed Broadcast Advertisements, www.fda.gov/cder/guidance/1804fnl.htm.

document explains that advertisers should have the ads reference a toll-free number, a website address, a concurrently running print ad, and health care professionals, as sources of labeling information.[176] It also clarifies that FDA's DTC advertising policy assumes, at minimum, that broadcast ads: (1) are not false or misleading, (2) present a fair balance between information about effectiveness and information about risk, (3) include a major statement conveying all of the product's most important risk information in consumer-friendly language, and (4) communicate all information relevant to a product's indication (including limitations on use) in consumer-friendly language.[177]

Although advertisers are required to submit their promotional materials to FDA around the time that the ads are circulated,[178] the Federal Food, Drug, and Cosmetic Act specifically prohibits FDA from requiring pre-approval to ensure compliance, except in "extraordinary circumstances,"[179] such as those listed in the regulations.[180] Nonetheless, FDA has devised a "voluntary" submission process, whereby "any advertisement may be submitted to the [FDA] prior to publication for comment,"[181] and it routinely requests that manufacturers submit initial launch ads before disseminating them.[182] Although these procedures are "voluntary," the majority of product sponsors comply with the pre-approval process for ads.[183]

Empirical data show that FDA's regulatory policy permitting DTC advertising: (1) improves the public health, (2) enhances the patient/physician relationship without interfering with the practice of medicine, (3) does not lead to misprescribing or over-prescribing, and (4) adequately communicates risk. Accordingly, the policy is advancing FDA's interest in protecting the public health.

However, FDA's disclosure requirements are consistent with First Amendment case law regarding compelled speech, such as *United Foods*, only to the extent that they are *necessary* to ensure that consumers are not misled.[184] FDA's advertising policies, in some instances, require excessive disclosure information and FDA should scrutinize carefully these policies to make certain that they pass constitutional muster.

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[176] *See id.* at 2-3; *see also* Consumer-Directed Broadcast Advertisements Guidance: Questions and Answers, August 1999, http://www.fda.gov/cder/guidance/1804q&a.htm

[177] Guidance for Industry: Consumer-Directed Broadcast Advertisements, www.fda.gov/cder/guidance/1804fnl.htm, at 2.

[178] *See* 21 C.F.R. § 314.81(b)(3) (2002).

[179] *See* 21 U.S.C. § 352(n)(3)(A); 21 C.F.R. § 202.1(j)(1) (2002).

[180] 21 C.F.R. § 202.1(j)(1) (2002).

[181] 21 C.F.R. § 202.1(j)(4) (2002) (emphasis added); *see* 61 Fed. Reg. 24314 (May 14, 1996).

[182] *See* 21 C.F.R. § 202.1(j)(4) (2002); FDA, Guidance to Expedite the Review of Launch Campaign Submissions (March 1994).

[183] *See* Ostrove Statement at 11. (Exh. 1).

[184] *See, e.g., United Foods*, 533 U.S. at 416.

In addition, the so-called "voluntary" pre-approval processes for ads and the initial launch ads, as well as the mandatory pre-approval process for ads that fall within FDA's "extraordinary circumstance" regulations, could be characterized as *de facto* or *de jure* prior restraints. As mentioned, prior restraints are the least tolerable infringement on First Amendment rights and there is a heavy presumption against their constitutionality.[185] Accordingly, these pre-approval processes must be truly voluntary. Moreover, to prevent these pre-approval processes from giving FDA unbridled discretion to reject proposed ads, in violation of advertisers' First Amendment rights, the pre-approval processes should incorporate procedural safeguards. FDA should have a formal process for voluntary submissions that, at minimum, delineates FDA's decision criteria and prescribes an FDA decision timetable. In addition, when rejecting an ad, FDA should be required to provide *empirical evidence* forming the basis for its rejection. FDA should not have unbridled discretion to reject ads that are truthful and nonmisleading and those that meet FDA's *constitutional* compelled speech requirements.

B. DTC Advertising Improves the Public Health.

DTC advertising improves the public health by providing benefits to patients and physicians. These benefits include:

- **Informing Patients/ Enabling Patients to Take Charge of Their Own Health** – DTC advertising informs consumers about serious medical conditions and available treatments. In fact, a 1999 FDA survey shows that about 50% of consumers sought out more information on a prescription drug after seeing an ad.[186] Additional information enables consumers to make informed decisions and to take charge of their own health, rather than relying on an increasingly complex and impersonal health care system.

- **Improving Patient/Physician Communication** – A recent study showed that 55% of physicians and 46% of patients believe that the ideal patient/physician relationship is a mutual partnership.[187] DTC advertising arms patients with valuable information, encouraging patient/physician dialogues that foster such partnerships.

  A recent survey has also shown DTC ads have encouraged 32% of consumers (61.1 million) to talk to their physicians.[188] Of those patients, 64% report that they always get information from their doctors about the risks associated with taking particular drugs.[189] Moreover, a

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[185] *See Nebraska Press Ass'n*, 427 U.S. at 559; *see also Southeastern Promotions*, 420 U.S. at 558-59.

[186] *Attitudes and Behaviors Associated with Direct-to-Consumer Promotion of Prescription Drugs: Main Survey Results*, FDA, Office of Medical Policy, Division of Drug Marketing, Advertising, and Communications, www.fda.gov/cder/ddmac/dtcindex.htm ("1999 FDA Survey"). (Exh. 2).

[187] *A Survey of the Patient-Physician Relationship in America*, Yankelovich Partners' Pfizer Medical Humanities Initiative (Dec. 1997) ("Yankelovich Study"). (Exh. 3).

[188] Wellness 2001: Direct to Consumer Advertising, A Consumer Perspective, Prevention Magazine ("Prevention Magazine (2001)").

[189] *International Survey on Wellness and Consumer Reaction to DTC Advertising of Rx Drugs*, Prevention Magazine (2000) ("Prevention Magazine (2000)").

study has also shown that 96% of physicians appreciate patients that are more informed about health problems and treatment options.[190]

- **Enabling Early Diagnosis** – DTC advertising raises consumer awareness of conditions and diseases that would otherwise go untreated. A Prevention Magazine study from 2000 shows that at least 20% of consumers, and as many as 32%, contact health care professionals based on information that they have learned from DTC advertising.[191] Moreover, a Prevention Magazine study from 2001 shows that about 24.8 million people have talked to their physicians about a medical condition for the first time, as a result of advertising.[192] The role DTC ads play in raising basic awareness is critically important. The American Diabetes Association estimates that six million people are unaware that they have diabetes, approximately one-third of patients with depression fail to seek treatment, and millions of Americans are unaware that they have high blood pressure.[193] Ads for erectile dysfunction have met with particular success. As of 2001, after such ads had aired for two years, millions of men talked to their physicians about using the drug. For every million men that requested the drug, physicians discovered that approximately 30,000 of the men had untreated diabetes, approximately 140,000 had untreated high blood pressure, and approximately 50,000 had untreated heart disease. Catching diseases early has immense benefits for families and ultimately for cost savings to the healthcare system.[194]

- **Patient Compliance** – The Prevention Magazine surveys from 2000 and 2001 reveal that approximately 17%-22% of patients are more likely to take their medicine because of ads, and are more likely to get prescriptions refilled.[195]

- **De-stigmatizing Diseases –** DTC ads that talk openly about diseases, such as depression, erectile dysfunction, and herpes, de-stigmatize the diseases and encourage patients to discuss them with their physicians.

- **Improves Appropriate Prescribing –** By encouraging patients to share more information with their doctors, DTC advertising gives physicians more information for appropriate

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[190] *See* Yankelovich Study. (Exh. 3).

[191] Prevention Magazine (2000).

[192] Prevention Magazine (2001).

[193] Testimony of Gregory J. Glover, M.D., J.D. Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Senate Committee on Commerce, Science, Transportation, U.S, Senate, July 24, 2001 (for PhRMA). (Exh. 4).

[194] *Inside the Industry- Rx Drugs: Healthy Profits, High Prices 'Irk' Consumers*, American Healthline, Apr. 27, 2000 (finding that physicians have increasingly used prescription drugs to treat chronic diseases, rather than more costly hospital care).

[195] Prevention Magazine (2001); Prevention Magazine (2000).

prescribing. A Kaiser Family Foundation study and a 1999 FDA survey have shown that physicians are still prescribing the most appropriate therapy.[196]

- **Lowers Costs of Prescription Drugs** – Research generally shows that advertising reduces prices because it makes markets more competitive. For example, in markets where there is competition, such as statin drugs, which reduce cholesterol, prices have been stable to slightly declining.[197] Moreover, evidence shows that "for every $1 increase in prescription drug expenditures in the U.S., there is a corresponding savings of $3.65 in hospital care expenditure . . . ."[198]

Accordingly, overly restrictive regulation of DTC advertising would do more than just violate the First Amendment – it would prevent consumers from receiving highly beneficial information.

C. DTC Advertising Does Not Interfere With the Practice of Medicine

Despite the changing nature of health care, the fundamental nature of the patient/physician relationship has remained the same, in that the physician is still the gatekeeper. Courts have recognized that the physician is still the best situated to communicate warning information to the patient because the physicians can personally convey information to the patient and quantify risk information based upon the medical profile of the patient.[199]

DTC advertising improves the patient/physician relationship without interfering with physician judgment and the practice of medicine. As noted, studies have shown that physicians are still prescribing the most appropriate therapy to patients who request products that they have seen in ads. For example, a Kaiser Family Foundation study revealed that only 44% of physicians actually prescribed the drug requested, 35% of physicians recommended a change in life-style, 25% recommended a different prescription drug, 19% recommended no drug at all, and 15% recommended an over-the-counter drug.[200] Moreover, another study concluded that:

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[196] *Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising*, The Henry J. Kaiser Family Foundation (Nov. 2001) ("Kaiser Family Foundation Study") (Exh. 5); *see also* 1999 FDA Survey (Exh. 2), *see infra*, discussions at Section VI(B).

[197] Testimony of John E. Calfee, Ph.D., Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Committee on Commerce, Science, and Transportation, U.S. Senate, July 24, 2001. (Exh. 6).

[198] Memorandum to the Association of National Advertisers, from Frank R. Lichtenberg, Professor of Business at the Columbia University Graduate School of Business, and Courtney C. Brown, Research Associate of the National Bureau of Economic Research, dated May 18, 2001, at 1. (Exh. 7).

[199] *See, e.g., Swayze v. McNeil Lab., Inc.*, 807 F.2d 464, 47 (5th Cir. 1987) (observing that increasing the manufacturer's duty to warn consumers "would only lead to confusion, and perhaps undermine the physician-patient relationship"); *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 357 (Ill. 1996) ("Prescribing physicians, and not pharmaceutical manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs"); *see also* Jack B. Harrison and Mina J. Jefferson, *"[S]ome [A]ccurate [I]nformation Is [B]etter Than [N]o [I]nformation [A]t [A]ll": Arguments Against An Exception to the Learned Intermediary Doctrine Based on Direct-To-Consumer Advertising*, 78 Or. L. Rev. 605 (Winter 1999).

[200] Kaiser Family Foundation Study (Exh. 5); *see also* 1999 FDA Survey (Exh. 2).

> DTC advertising is not burdening physicians with patients who ask inappropriate questions about their health needs. It is not flooding physicians with inappropriate prescription requests. It is not producing uninformed or misinformed patients, nor is it diminishing the overall value of the patient's visit with the healthcare provider.[201]

In fact, that same study found that a majority of physicians feel DTC advertising enhances the quality of the patient visit.[202]

D. DTC Advertising Does Not Lead To Misprescribing or Over-Prescribing.

Despite assertions by critics that DTC advertising can lead to misprescribing or over-prescribing, Nancy Ostrove, Ph.D., the former Deputy Director of FDA's Division of Drug Marketing, Advertising, and Communications, testified before Congress that there is no evidence that DTC advertising is increasing inappropriate prescribing.[203] Dr. Ostrove was relying on an FDA study that suggested, to the contrary, that "physicians are comfortable denying prescriptions when the prescription would not be right for the patient." Notably, the results of the 1999 FDA survey, regarding the manner in which physicians handled patient requests for particular drugs that have been advertised, were consistent with those in the Kaiser Family Foundation study mentioned above.[204] The results of these studies make sense. DTC advertising does not alter physician control over, or responsibility for, prescribing.[205] Patients must still get prescriptions from physicians, and physicians are still bound by ethical duties to act in the best interest of the patient. Physicians who fail to do so are subject to malpractice laws.

Any additional regulation of DTC advertising based upon the unsubstantiated fear that such advertising leads to misprescribing and over-prescribing would run afoul of the First Amendment. Like the government in *Edenfield*, FDA has no evidence that such regulation would directly and materially advance its interest of protecting public health.[206] Moreover, the Supreme Court, in *Western States*, flatly rejected the argument that advertising compounded drugs would cause patients to talk doctors into prescribing unnecessary drugs because it merely amounted to a fear that people would use truthful information "irrationally."[207] In rejecting that argument, the Court noted that "[the] First Amendment directs the [Court] to be especially skeptical of regulations that seek to keep

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[201] *DTC Cholesterol and Mood Anxiety Disorders, Doctor Dialogues*, Market Measures Interactive L.P., July 2001 (Executive Summary). (Exh. 8).

[202] *See* Kaiser Family Foundation Study. (Exh. 5).

[203] *See* Ostrove Statement, at 17. (Exh. 1).

[204] *Compare* Kaiser Family Foundation Study (Exh. 5), *with* 1999 FDA Survey (finding that 50% of the patients received the drug discussed, 32% received a different prescription drug, 29% received behavioral or life-style change suggestions from the physician, 14% received a recommendation for an OTC drug, and 15% received no drug) (Exh. 2).

[205] *See* Jack B. Harrison, *supra*, at note 199.

[206] *Edenfield*, 507 U.S. at 777.

[207] *Western States*, 122 S. Ct. at 1507-08 (citing *44 Liquormart*, 517 U.S. at 503).

people in the dark for what the government perceives to be their own good."[208] Accordingly, any similar argument advanced by FDA for DTC advertising would fail.

In addition, given that empirical evidence indicates that FDA's regulatory scheme for DTC advertising does not lead to misprescribing or over-prescribing, any additional requirements on DTC advertising imposed by FDA, involving compelled speech or other restrictions, would be more extensive than necessary in violation of the First Amendment.

E. DTC Advertising Adequately Communicates Risk.

Surveys show that FDA's DTC advertising disclosure requirements (*i.e.*, the *brief summary* requirement for print advertising and the *major risk* and *adequate provision* requirements for broadcast advertising) adequately communicate risk. John E. Calfee, Ph.D., from the American Enterprise Institute, reviewed a series of surveys, relying primarily upon the 1999 FDA survey and the 1999 and 2000 Prevention Magazine surveys and concluded:

> Advertising did not tend to suppress risk information. In the FDA survey, for example, the recall rate for risk information (82%) was nearly as high as that for benefits (87%). Seventy percent *disagreed* with the statement that DTC ads "make it seem like a doctor is not needed to decide whether a drug is right for me." Respondents tended to pay considerable attention to detailed risk information in print ads. In the FDA survey, 40% read half or more of the information, and 85% said they would read all or almost all of the information if they were especially interested in the drug.[209]

Dr. Calfee also observed that the 1999 *Prevention* [Prevention Magazine] results were similar, as were those from the AARP survey.[210]

Any additional restrictions on DTC advertising based upon the unsubstantiated fear that such advertising fails to communicate risk, would contravene the holding in *Edenfield*,[211] requiring that restrictions on speech be evidence-based, and the notion articulated in *Western States* that regulations should not be based on fears that the public will use truthful information "irrationally."[212] Moreover, given that empirical evidence indicates that FDA's regulatory scheme for DTC advertising adequately communicates risk, any additional requirements for DTC advertising imposed by FDA, involving compelled speech or other restrictions, would be more extensive than necessary in violation of the First Amendment.

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[208] *Id.*

[209] John E. Calfee, Ph.D., *What Consumer Surveys Show About Direct-to Consumer Advertising of Prescription Drugs*, American Enterprise Institute, May 7, 2001, at 2. (Exh. 9).

[210] *See id.*

[211] *Edenfield*, 507 U.S. at 777.

[212] *Western States*, 122 S. Ct. at 1507-08.

VIII. The Existing Regulatory Schemes for FDA-Regulated Products Appropriately Distinguish Between Labeling and Advertising.

Question six in FDA's request for comments asks what legal arguments or social science, if any, provide support for distinguishing between labeling and advertising, and whether FDA should have greater control over labeling. FAC believes that it is appropriate to distinguish between labeling and advertising for FDA-regulated products and that FDA has appropriately asserted greater control over labeling.

Generally, FDA's compulsion of more speech for labeling than advertising is justified given the different market roles of labeling and advertising. Labeling is the consumers' last resource, and its purpose is to inform, instruct, and warn consumers about the nature of the product and associated risks. Thus, labeling may be materially misleading if it omits facts that would simply inform the consumer, such as ingredients. Accordingly, FDA's extensive compelled speech requirements for labeling are constitutional under *United Foods* -- to the extent that they are necessary to prevent the consumer from being misled and to keep the consumer informed about the product.

Notably, however, FDA should scrutinize its labeling schemes for unnecessary requirements that infringe on commercial speech rights. For example, the breadth of FDA's definition of "labeling"[213] in the context of prescription drugs requires more disclosure than necessary for certain items that are not used as last resources, such as calendars distributed to health care professionals. FDA has also cast its "labeling" net too broadly in the context of food. For example, FDA, in its 2001 warning letter to Ocean Spray Cranberries, Inc. ("Ocean Spray"), asserted jurisdiction over health claims that Ocean Spray made on the Internet.[214] Given that Internet ads for juice products are not a last health resource for consumers, such ads should not be considered "labeling," and should be under the jurisdiction of the FTC, which handles food advertising.[215]

Advertising, on the other hand is the first resource. It piques consumer interest in a product, and then informs consumers about places where they can get more information. For example, in the context of prescription drug advertising, from the time that the consumer sees the ad, to the time that he ingests or uses the product, he can get more information from the labeling or from a physician. Therefore, the lesser compelled speech requirements for prescription drug advertising (as opposed to labeling) are sufficient to further the public health.

IX. Regulating Commercial Speech on the Internet

Although FDA's request for comments does not expressly address regulation of Internet promotions, FAC would like to take this opportunity to address its First Amendment concerns related to that area.

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[213] *See* 21 C.F.R. § 202.1(l) (2002).

[214] FDA Warning Letter to Ocean Spray, dated Jan. 19, 2001.

[215] Working Agreement Between FTC and FDA (1971) (giving FDA jurisdiction over food labeling and the FTC jurisdiction over food advertising).

A. The Internet Has Become A Major Source of Health-Related Information.

It is estimated that by the end of 1997, more than 100 million people were already using the Internet, and that since that time Internet traffic has doubled every 100 days. This traffic has had a major impact on the dissemination of health-related information. A recent study found that more than 90 million people have used the Internet for health-related information.[216] Moreover, manufacturers and advertisers of foods, dietary supplements, drugs, medical devices, and cosmetics along with manufacturers and advertisers of many other consumer goods, have set up websites to provide consumers with more information about their products; physicians have used the Internet to communicate with other researchers; and pharmacies have set up websites to actually sell drugs. It is estimated that Internet pharmacies will generate approximately $15 billion in sales by the year 2004.[217]

B. Regulation of Information Presented on the Internet.

1. Jurisdictional Issues

FDA and the FTC have yet to determine whether Internet promotion constitutes labeling or advertising, although they have been working to develop guidance on the subject. Largely skirting the issue altogether in their actions to date, FDA and the FTC have teamed up in a program called Operation Cure.All, which polices fraudulent and misleading health claims on the Internet. As of September 2001, under Operation Cure.All, the FTC had brought 13 actions against Internet marketers, including several dietary supplement firms, making false or unsubstantiated health claims, and the FDA's efforts "to curtail online marketing of unapproved drugs [had] resulted in at least 12 product seizures, 11 product recalls, 43 arrests and 22 convictions."[218] FDA has also taken action against Internet marketing of approved products for unapproved uses as well as otherwise misleading or unsupported claims.[219]

In settling this jurisdictional issue, or indeed, in determining whether to apply the regulations for labeling or advertising in the context of prescription drugs and "restricted devices," FDA should consider the different roles that labeling and advertising play in the market and the restrictions imposed by the First Amendment – and it should refrain from casting its "labeling" net too broadly, as it did with the Ocean Spray warning letter.[220] As mentioned, pursuant to the Supreme Court decision in *United Foods*, compelled expression is unconstitutional if it is not necessary to make the promotion at issue nonmisleading.[221] Accordingly, FDA should scrutinize how much disclosure, or

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[216] *Health Claims on the Internet: Buyer Beware*, FTC Consumer Feature (June 2001).

[217] James M. Wood and Howard L. Dorfman, *"Dot.Com Medicine" – Labeling in an Internet Age*, 56 Food & Drug L.J. 143 (2001).

[218] Linda Bren, *Agencies Team Up in War Against Internet Health Fraud*, FDA Consumer Magazine (September-October 2001).

[219] *See supra*, James M. Wood and Howard Dorfman, at 148, at note 217.

[220] *See* FDA Warning Letter to Ocean Spray, dated Jan. 19, 2001.

[221] *See United Foods*, 533 U.S. at 416.

information, is necessary to make the promotion at issue non-misleading. It is not necessary for every website to contain all of the information required by FDA's labeling regulations. Further, FDA should not impose additional requirements that would not pass constitutional muster under *Central Hudson.*[222]

2. Provision of Health Information/Scientific Exchange Versus Commercial Speech.

As mentioned, although there is a strong argument that infringement on truthful, nonmisleading commercial speech should be subject to strict scrutiny, courts have not yet broken new ground and have applied the intermediate scrutiny standard in *Central Hudson.*[223] Therefore, to ensure that its developing guidance document on Internet promotions does not violate the First Amendment, FDA should give consideration to when the provision of health or scientific information on the Internet constitutes core protected speech and when it constitutes commercial speech. As mentioned, the dividing line between commercial speech and core protected speech is not always clear, particularly where manufacturers are directing consumer's attention to independent scientific studies. This gray area raises an abundance of questions, such as: (1) is there a way to distinguish between the presentation of information about investigational products and uses for scientific and promotional purposes? (2) does a manufacturer's use of a "link" to a scientific paper posted on an academic or government site make the scientific paper commercial speech? (3) is a summary of the same study, posted on the manufacturers website commercial speech? and (4) is a summary of a study involving a commercial product, which is posted on an academic or government website, commercial speech?[224] In addressing these questions, FDA should carefully consider the degree to which its actions may be constrained by the First Amendment, paying particular attention to whether the communications that may be affected are core protected speech or whether they do "no more than propose a commercial transaction" – the test for identifying commercial speech.[225]

In addition, FDA should consider that even when health-related or scientific speech constitutes commercial speech, *Western States* and *Edenfield* instruct that restrictions thereof are unconstitutional if the restrictions do not directly and materially advance the FDA's interests[226] and if FDA could "achieve its interests in a manner that does not restrict speech, or restricts less speech."[227]

X. Other Product Areas

FDA should be mindful of the First Amendment parameters discussed herein if: (1) it works with other agencies to implement policies that potentially infringe on commercial speech rights, and (2) it

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[222] *See Western States*, 122 S. Ct. at 1504 (reciting and reconfirming the *Central Hudson* test).

[223] *See supra*, discussion at Section II(A).

[224] *See supra*, James M. Wood and Howard Dorfman (generally), at note 217.

[225] *Virginia State Bd. of Pharmacy*, 425 U.S. at 762 (*quoting Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 385 (1973)).

[226] *Edenfield*, 507 U.S. at 770-761; *see also Lorillard Tobacco*, 533 U.S. at 55 (quoting *Edenfield* for this proposition).

[227] *Western* States, 122 S. Ct. at 1506.

implements policies that potentially infringe on commercial speech for any product that falls under its jurisdiction in the future. For example, although the Bureau of Alcohol, Tobacco, and Firearms ("BATF") has jurisdiction over labeling for alcoholic beverages and shares jurisdiction with the FTC over advertising for alcoholic beverages,[228] the BATF frequently consults with FDA regarding health-related issues.[229] To the extent that FDA advises BATF, it should consider the First Amendment parameters in *Central Hudson* and its progeny (regarding infringement on commercial speech generally), *United Foods* (regarding compelled commercial speech), and *Southeastern Promotions* (regarding prior restraints on speech).

XI. Conclusions

Free speech is fundamental to our American way of life, and accordingly, FAC applauds FDA efforts to determine whether its policies unconstitutionally infringe commercial speech. FAC respectfully urges FDA to scrutinize the policies identified herein that may run afoul of the First Amendment and to incorporate a First Amendment analysis into every future action that potentially restricts, suppresses, or infringes on commercial speech.

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[228] Federal Alcohol Administration Act ("FAA"), 27 U.S.C. § 205(e) (Supp. 2002); 15 U.S.C. §§ 45-58 (Supp. 2002).

[229] *See, e.g.*, Industry Circular: Health Claims in the Labeling and Advertising of Alcoholic Beverages, No. 93-8, BATF, Aug. 2, 1993 (describing the development of a consultation process with FDA); FDA Compliance Policy Guide No. 7155g.04, Nov. 20, 1987 (describing the consultation process regarding recalls); 39 Fed. Reg. 36127 (Oct. 8, 1974) (memorandum of understanding confirming that BATF has primary jurisdiction for labeling but stating that BATF should consult FDA in developing labeling regulations).

APPENDIX

Exhibit 1 Testimony of Nancy M. Ostrove, Ph.D., Deputy Director Division of Drug Marketing, Advertising and Communications, Center for Drug Evaluation and Research, FDA, Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Senate Committee on Commerce, Science, Transportation, U.S, Senate, July 24, 2001

Exhibit 2 Attitudes and Behaviors Associated with Direct-to-Consumer Promotion of Prescription Drugs: Main Survey Results, FDA Office of Medical Policy, Division of Drug Marketing, Advertising, and Communications (1999)

Exhibit 3 *A Survey of the Patient-Physician Relationship in America*, Yankelovich Partners' Pfizer Medical Humanities Initiative (Dec. 1997)

Exhibit 4 Testimony of Gregory J. Glover, M.D., J.D. Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Senate Committee on Commerce, Science, Transportation, U.S, Senate, July 24, 2001

Exhibit 5 *Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising*, The Henry J. Kaiser Family Foundation (Nov. 2001)

Exhibit 6 Testimony of John E. Calfee, Ph.D. Before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Senate Committee on Commerce, Science, Transportation, U.S, Senate, July 24, 2001

Exhibit 7 Memorandum of the Association of National Advertisers from Frank R. Lichtenberg, Professor of Business at the Columbia University Graduate School of Business, and Courtney C. Brown, Research Associate of the National Bureau of Economic Research, dated May 18, 2001

Exhibit 8 *DTC Cholesterol and Mood Anxiety Disorders, Doctor Dialogues,* Market Measures Interactive L.P., July 2001 (Executive Summary)

Exhibit 9 John E Calfee, Ph.D., *What Consumer Surveys Show About Direct-to Consumer Advertising of Prescription Drugs,* American Enterprise Institute, May 7, 2001